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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,227	12/15/2003	Jonathan Alexander Terrett	2543-1-033	3125

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,227

Applicant(s)

TERRETT, JONATHAN
ALEXANDER

Examiner

Alana M. Harris, Ph.D.

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1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 17-19 and 21, drawn to an isolated polypeptide and a medicament comprising said polypeptide identified as SEQ ID NO: 1, classified in class 530, subclass 350.
 - II. Claims 4-6, 17-19 and 21, drawn to an isolated or recombinant nucleic acid molecule, SEQ ID NO: 2 and a medicament comprising said sequence, classified in class 536, subclass 23.5.
 - III. Claim 7, drawn to a method for screening and/or diagnosing breast cancer comprising detecting and /or quantifying an amount of a polypeptide identified as SEQ ID NO: 1, classified in class 435, subclass 7.1.
 - IV. Claim 7, drawn to a method for screening and/or diagnosing breast cancer comprising detecting and /or quantifying an amount of a nucleic acid identified as SEQ ID NO: 4, classified in class 435, subclass 6.
 - V. Claims 8-10, 17-19 and 21, drawn to an antibody that binds SEQ ID NO: 1 and a medicament comprising said antibody, classified in class 530, subclass 387.3.
 - VI. Claims 11-15, drawn to a method of screening for agents capable of interacting with a polypeptide identified as SEQ ID NO: 1, classified in class 436, subclass 64.
 - VII. Claim 16-19 and 21, drawn to an agent which alters the expression and/or activity of a polypeptide identified as SEQ ID NO: 1 and medicament for

use in prophylaxis and/or treatment of cancer comprising an agent capable of modulating the expression and/or activity of said polypeptide, classified in class 436, subclass 94.1.

- VIII. Claim 16-19 and 21, drawn to an agent which alters the expression and/or activity of a nucleic acid identified as SEQ ID NO: 2 and medicament comprises an agent capable of modulating the expression and/or activity of a nucleic acid molecule which has substantial identity to SEQ ID NO: 2, classified in class 424, subclass 1.73.
- IX. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 9.1.
- X. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering a nucleic acid having substantial identity to SEQ ID NO: 2, classified in class 424, subclass 64.
- XI. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an antibody, classified in class 424, subclass 178.1.
- XII. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 94.1.

XIII. Claim 20, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a nucleic acid molecule identified as SEQ ID NO: 2, classified in class 424, subclass 1.73.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I, II, V-VIII, IX and X are structurally and functionally different products, which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Furthermore, the products of Group I are polypeptides, the products of Group II are DNA, deoxyribonucleic acids, unbranched polymers composed of four subunits, whereas the antibody product of Group III are a complex of glycoproteins. The agent of Group VI could be an enzyme inhibitor, whereas the agent of Group VII could be a small inhibitory RNA (siRNA), which could turn off the activity of a gene.

Inventions III, IX and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody of Group V could be used in the *in vitro* method of Group III or in the *in vivo* method of Group IX.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups IV and VI have the same method endpoint, screening and/or diagnosing breast cancer, however they each implement different and patentably distinct products to achieve the endpoint. Furthermore, the same endpoint may be arrived at using electron microscopy.

Inventions IX-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups IX-XIII have the same method endpoint, treating breast cancer in a subject, however they each use different and patentably distinct products.

2. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
22 September 2006